Complete Summary

GUIDELINE TITLE

Treatment of stage II non-small cell lung cancer.

BIBLIOGRAPHIC SOURCE(S)

Scott WJ, Howington J, Movsas B. Treatment of stage II non-small cell lung cancer. Chest 2003 Jan;123(1 Suppl):188S-201S. [52 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Stage II non-small cell lung cancer

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Oncology
Pulmonary Medicine
Radiation Oncology
Thoracic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide clinically relevant, evidence-based guidelines for the treatment of stage II non-small cell lung cancer

TARGET POPULATION

Patients with stage II non-small cell lung cancer (NSCLC)

INTERVENTIONS AND PRACTICES CONSIDERED

Stage II Non-small Cell Lung Cancer (NSCLC) (T1-2N1M0)

Sleeve lobectomy for patients with N1 lymph node metastases in whom a complete resection can be achieved.

Adjuvant Therapy

Postoperative radiotherapy

Therapies Considered but Not Recommended

Pneumonectomy

Therapies Considered but Should be Limited to Clinical Trials

1. Postoperative chemotherapy
2. Postoperative combined chemotherapy and radiotherapy
3. Preoperative chemotherapy followed by surgery for patients with T2N0, T1-2N1, and T3N0 NSCLC

Stage II (T3 [chest wall]) non-small cell lung cancer

1. Surgical exploration to confirm lung tumors that abut or are adjacent to the chest wall.
2. En bloc resection (tumors that extend beyond the parietal pleura).
3. Extrapleural resection (tumors that do not extend beyond the parietal pleura).

Adjuvant Therapy

Postoperative radiotherapy (patients with incomplete resection or resection with a negative or close margin)

Therapies Considered but Not Recommended

1. Discontinuous or non-en bloc resection
2. Routine postoperative radiotherapy for patients who have undergone a complete resection.
3. Use of computed tomography assessment alone to predict the presence of chest wall invasion

T3 (mediastinal) NSCLC

1. Histological assessment of mediastinal lymph nodes prior to resection.
2. Postoperative radiotherapy (following incomplete resection).

Therapies Considered but Not Recommended

Adjuvant radiotherapy for completely resected patients.

MAJOR OUTCOMES CONSIDERED

- 5-year survival rate
- Local recurrence rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

As a first step in identifying the evidence for each topic, the guideline developers sought existing evidence syntheses including guidelines, systematic reviews, and meta-analyses. They searched computerized bibliographic databases including MEDLINE, Cancerlit, CINAHL and HealthStar, the Cochrane Collaboration Database of Abstracts of Reviews of Effectiveness, the National Guideline Clearinghouse, and the National Cancer Institute Physician Data Query database. Computerized searches through July 2001 used the MeSH terms lung neoplasms (exploded) and bronchial neoplasms or text searches for lung cancer combined with review articles, practice guidelines, guidelines, and meta-analyses. They also searched and included studies from the reference lists of review articles, and queried experts in the field. An international search was conducted of Web sites of provider organizations that were likely to have developed guidelines. Abstracts of candidate English language articles were reviewed by two physicians (one with methodological expertise and one with content area expertise) and a subset was selected for review in full text. Full-text articles were reviewed again by two physicians to determine whether they were original publications of a synthesis and were pertinent to at least one of the topics of the guideline. Articles described as practice guidelines, systematic reviews, or meta-analyses were included, as were review articles that included a "Methods" section. Included articles were classified according to topic.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The United States Preventive Services Task Force (USPSTF) scheme offers general guidelines to assign one of the following grades of evidence: good, fair, or poor. In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between. In addition to the strength of the study design, however, study quality also was considered. The United States Preventive Services Task Force approach considers well-recognized criteria in rating the quality of individual studies for a variety of different types of study design (e.g., diagnostic accuracy studies and case-control studies). The thresholds for distinguishing good vs fair and fair vs poor evidence are not explicit but are left to the judgment of panelists, reviewers, and members of the executive committee.

Assessment of the Scope and Quality of Clinical Practice Guidelines

Clinical practice guidelines identified from the systematic search were evaluated by at least four reviewers using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each writing committee received a comprehensive list of existing systematic reviews and meta-analyses as well as guidelines published by other groups. In addition, for five key topics (prevention, screening, diagnosis, and staging [invasive and noninvasive]), new systematic reviews were undertaken (see "Description of Methods Used to Collect the Evidence" and "Description of Methods Used to Analyze the Evidence" fields). For all other topics, writing committees were responsible for identifying and interpreting studies that were not otherwise covered in existing syntheses or guidelines.

The guidelines developed by the writing committee were distributed to the entire expert panel, and comments were solicited in advance of a meeting. During the

meeting, proposed recommendations were reviewed, discussed, and voted on by the entire panel. Approval required consensus, which was defined as an overwhelming majority approval. Differences of opinion were accommodated by revising the proposed recommendation, the rationale, or the grade until consensus could be reached. The evidence supporting each recommendation was summarized, and recommendations were graded as described. The assessments of level of evidence, net benefit, and grade of recommendation were reviewed by the executive committee.

Values

The panel considered data on functional status, quality and length of life, tolerability of treatment, and relief of symptoms in formulating guideline recommendations. Cost was not explicitly considered in the guideline development process. Data on these outcomes were informally weighted, without the use of explicit decision analysis or other modeling. The values placed on types of outcomes varied with clinical scenarios. For example, in some situations they considered life expectancy, such as the effects of early detection. In other situations they weighed quality of life more heavily, such as in palliative care and in interpreting small increases in life expectancy with chemotherapy for stage IV disease.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The guideline developer´s grading scheme is a modification of the United States Preventive Services Task Force (USPSTF) grades to allow recommendations for a service when (1) evidence is poor, (2) the assessment of the net benefit is moderate to high, and (3) there is consensus among the expert panel to recommend it. This change was necessary because, unlike preventive services (i.e., the routine offering of tests or treatments to well people) in which the burden of proof is high, clinical decisions about the treatment of patients with lung cancer often must be based on an interpretation of the available evidence, even if it is of poor quality. This adaptation distinguished between interventions with poor evidence for which there is consensus (grade C) and interventions with poor evidence for which there is not consensus (grade I).

Grades of Recommendations and Estimates of Net Benefit

The grade of the strength of recommendations is based on both the quality of the evidence and the net benefit of the service (i.e., test, procedure, etc.).

Grade A The panel strongly recommends that clinicians routinely provide [the service] to eligible patients. An "A" recommendation indicates good evidence that [the service] improves important health outcomes and that benefits substantially outweigh harms.

Grade B The panel recommends that clinicians routinely provide [the service] to eligible patients. A "B" recommendation indicates at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

Grade D The panel recommends against clinicians routinely providing [the service]. A "D" recommendation indicates at least fair evidence that [the service] is ineffective or that harm outweighs benefit.

Grade I The panel concludes that the evidence is insufficient to recommend for or against [the service]. An "I" recommendation indicates that evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined, and that the panel lacked a consensus to recommend it.

Net Benefit

The levels of net benefit are based on clinical assessment. Estimated net benefit may be downgraded based on uncertainty in estimates of benefits and harms.

Substantial Benefit: Benefit greatly outweighs harm

Moderate Benefit: Benefit outweighs harm

Small/weak Benefit: Benefit outweighs harm to a minimally clinically important degree

None/negative Benefit: Harms equal or outweigh benefit, less than clinically important

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After extensive review within the expert panel and executive committee, the guidelines were reviewed and approved by the American College of Chest Physicians (ACCP) Health and Science Policy Committee and then by the American College of Chest Physicians Board of Regents.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is rated based on the levels of evidence (good, fair, poor), net benefit (substantial, moderate, small/weak, none/negative), and the grades of the recommendations (A, B, C, D, I). Definitions are presented at the end of the "Major Recommendations" field.

1. For patients with N1 lymph node metastases in whom a complete resection can be achieved with either technique, sleeve lobectomy is recommended over pneumonectomy. Level of evidence, poor; benefit, moderate; grade of recommendation, C
2. For patients who have undergone complete resection of stage II non-small cell lung cancer (NSCLC) with N1 lymph node metastases (stage II [N1] NSCLC), routine administration of postoperative radiation therapy with a goal of improving survival is not recommended. Level of evidence, fair; benefit, none/negative; grade of recommendation, D
3. For patients who have undergone complete resection of stage II NSCLC with N1 lymph node metastases (stage II [N1] NSCLC), routine administration of postoperative radiation therapy (i.e., adjuvant radiation therapy) decreases local recurrence rates. For patients who have undergone complete resection of stage II NSCLC with N1 lymph node metastases (stage II [N1] NSCLC), routine administration of postoperative radiation therapy can be used if the goal is to decrease local recurrence with the understanding that survival will not be improved. Level of evidence, fair; benefit, small; grade of recommendation, C
4. For patients who have undergone complete resection of stage II NSCLC with N1 lymph node metastases (stage II [N1] NSCLC), the evidence indicates that adjuvant radiotherapy improves local control but does not increase survival. An overall recommendation cannot be made regarding routine use of adjuvant radiotherapy in this setting. Level of evidence, fair; benefit, none/negative; grade of recommendation, D
5. For patients who have undergone complete resection of stage II NSCLC, administration of postoperative chemotherapy should not be considered standard therapy at this time, and its use should be limited to patients enrolled in clinical trials. Level of evidence, good; benefit, none/negative; grade of recommendation, D
6. In patients who have undergone complete or incomplete resection of stage II NSCLC, postoperative combined chemotherapy and radiotherapy should not be considered standard therapy at this time, and their use should be limited to patients enrolled in clinical trials. Level of evidence, good; benefit, none/negative; grade of recommendation, D
7. For patients with stage T2N0, T1-2N1, and T3N0 NSCLC, routine use of preoperative chemotherapy followed by surgery should not be considered standard therapy at this time, and its use should be limited to patients enrolled in clinical trials. Level of evidence, poor; benefit, none/negative; grade of recommendation, I
8. For patients with lung tumors that abut or are adjacent to the chest wall based on chest computed tomography (CT) (clinical T3 [chest wall] NSCLC), the presence or absence of chest wall invasion should not be assumed based on computed tomography findings alone but should be confirmed by surgical exploration. Level of evidence, poor; benefit, moderate; grade of recommendation, C
9. For patients with T3 (chest wall) NSCLC that, at the time of operation, may extend beyond the parietal pleura, en bloc resection of T3 (chest wall) NSCLC must be performed unless one is confident that extrapleural invasion does not

exist. Long-term survival after surgical treatment for T3 (chest wall) NSCLC is highly dependent on the completeness of resection. Level of evidence, poor; benefit, substantial; grade of recommendation, C

10. For patients with T3 (chest wall) NSCLC that does not extend beyond the parietal pleura, an extrapleural resection may be performed. As long as a complete resection is achieved, survival following extrapleural resection is similar to that achieved following en bloc resection. Level of evidence, poor; benefit, substantial; grade of recommendation, C
11. At the time of surgery for T3 (chest wall) NSCLC suspected of invading beyond the parietal pleura, separation of the tumor from the chest wall followed by resection of that portion of the chest wall that the tumor was originally adherent to (i.e., discontinuous or non-en bloc resection) should be avoided. Limited data suggest that a discontinuous resection results in very inferior survival compared to en bloc resection. Level of evidence, poor; benefit, substantial; grade of recommendation, C
12. For patients who have undergone complete resection of T3 (chest wall) NSCLC, routine postoperative radiotherapy does not provide a documented survival benefit and should not be used in these patients. Level of evidence, poor; benefit, none/negative; grade of recommendation, I
13. In patients who have undergone incomplete resection (or resection with a negative but close margin) of T3 (chest wall) NSCLC, postoperative radiotherapy may provide a survival benefit and could be used. Level of evidence, poor; benefit, small; grade of recommendation, C
14. For patients with T3 (mediastinal) NSCLC who have undergone incomplete resection, postoperative radiotherapy may be of benefit. Level of evidence, poor; benefit, small; grade of recommendation, C
15. Adjuvant radiotherapy for T3 (mediastinal) NSCLC for completely resected patients should not be performed. Level of evidence, poor; benefit, none/negative; grade of recommendation, I
16. In all patients with centrally located clinical T3 NSCLC, histologic assessment of mediastinal mediastinal lymph nodes should be performed prior to resection. Preoperative identification of N2 lymph node metastases precludes surgical resection as initial therapy in this setting. Level of evidence, poor; benefit, substantial; grade of recommendation, C

Definitions:

Levels of Evidence

In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between.

Grades of Recommendations and Estimates of Net Benefit

The grade of the strength of recommendations is based on both the quality of the evidence and the net benefit of the service (i.e., test, procedure, etc.).

Grade A The panel strongly recommends that clinicians routinely provide [the service] to eligible patients. An "A" recommendation indicates good evidence that

[the service] improves important health outcomes and that benefits substantially outweigh harms.

Grade B The panel recommends that clinicians routinely provide [the service] to eligible patients. A "B" recommendation indicates at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

Grade D The panel recommends against clinicians routinely providing [the service]. A "D" recommendation indicates at least fair evidence that [the service] is ineffective or that harm outweighs benefit.

Grade I The panel concludes that the evidence is insufficient to recommend for or against [the service]. An "I" recommendation indicates that evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined, and that the panel lacked a consensus to recommend it.

Net Benefit

The levels of net benefit are based on clinical assessment. Estimated net benefit may be downgraded based on uncertainty in estimates of benefits and harms.

Substantial Benefit: Benefit greatly outweighs harm

Moderate Benefit: Benefit outweighs harm

Small/weak Benefit: Benefit outweighs harm to a minimally clinically important degree

None/negative Benefit: Harms equal or outweigh benefit, less than clinically important

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

These guideline recommendations may assist physicians in achieving the best possible outcomes for their patients, given the knowledge and capabilities at this time.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Stage II non-small cell lung cancer consists of a number of different groups of patients. Because of this and because only 5 to 10% of all patients with non-small cell lung cancer are classified as stage II, the quality of the evidence for certain recommendations listed here is limited. Other limitations of these guidelines include the fact that it is not possible to include all of the varied clinical situations that a practicing physician is likely to encounter in a document such as this, and that ongoing research may render sections of these guidelines obsolete not long after they are published.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

1. The American College of Chest Physicians (ACCP) is developing a set of PowerPoint slide presentations for physicians to download and use for physician and allied health practitioners education programs.
2. The ACCP is developing a Quick Reference Guide (QRG) in print and PDA formats for easy reference.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scott WJ, Howington J, Movsas B. Treatment of stage II non-small cell lung cancer. Chest 2003 Jan;123(1 Suppl):188S-201S. [52 references] PubMed

ADAPTATION

Not applicable: Guideline was not adapted from another source.

DATE RELEASED

2003 Jan

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

The guideline development panel was composed of members and nonmembers of the American College of Chest Physicians (ACCP) who were known to have expertise in various areas of lung cancer management and care, representing multiple specialties from the following 13 national and international medical associations:

- Alliance for Lung Cancer Advocacy, Support, and Education (a patient support group)
- American Association for Bronchology
- American Cancer Society
- American College of Physicians
- American College of Surgeons Oncology Group
- American Society of Clinical Oncology
- American Society for Therapeutic Radiology and Oncology
- American Thoracic Society
- Association of Community Cancer Centers
- Canadian Thoracic Society
- National Comprehensive Cancer Network
- Oncology Nurses Society
- Society of Thoracic Surgeons

The specialties included pulmonary/respiratory medicine, critical care, medical oncology, thoracic surgery, radiation oncology, epidemiology, law, and medical ethics.

SOURCE(S) OF FUNDING

Funding for both the evidence reviews and guideline development was provided through an unrestricted educational grant from Bristol-Myers Squibb, which had no other role in the evidence review or guideline development process or content.

GUIDELINE COMMITTEE

American College of Chest Physicians (ACCP) Expert Panel on Lung Cancer Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Walter J. Scott, MD, FCCP; John Howington, MD, FCCP; Benjamin Movsas, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Information about potential conflicts of interest were collected from each member of the expert panel or writing committee at the time of their nomination in accordance with the policy of the American College of Chest Physicians (ACCP). Information on conflicts of interest for each panelist is listed in the guideline.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Background Articles

- Alberts WM. Lung cancer guidelines. Introduction. Chest 2003 Jan;123(1 Suppl):1S-2S
- McCrory DC, Colice GL, Lewis SZ, Alberts WM, Parker S. Overview of methodology for lung cancer evidence review and guideline development. Chest 2003 Jan;123(1 Suppl):3S-6S.
- Harpole LH, Kelley MJ, Schreiber G, Toloza EM, Kolimaga J, McCrory DC. Assessment of the scope and quality of clinical practice guidelines in lung cancer. Chest 2003 Jan;123(1 Suppl):7S-20S.
- Alberg AJ, Samet JM. Epidemiology of lung cancer. Chest 2003 Jan;123(1 Suppl):21S-49S.

Electronic copies: Available to subscribers of Chest - The Cardiopulmonary and Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 3, 2003. The information was verified by the guideline developer on October 1, 2003.

COPYRIGHT STATEMENT

Date Modified: 11/15/2004